

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Manfred Bohn et al.

Serial No. 09/077,194

Filing Date: May 26, 1998

**USE OF 1-HYDROXY-2-PYRIDONES
FOR THE TREATMENT OF
SEBORRHEIC DERMATITIS**

DECLARATION OF KEVIN KRIEL

I, Kevin Kriel, do hereby declare that:

1. I have been employed by Medicis Pharmaceutical Corporation ("Medicis") since November 2002, and was a consultant to Medicis from January 2002 to November 2002. I am currently Senior Product Manager, and am responsible for the sales and marketing of Loprox® Shampoo. I am also a registered pharmacist and hold a degree in pharmacy from Albany College of Pharmacy. According to legal counsel, Loprox® Shampoo is a ciclopirox-containing shampoo covered by claims 38, 39, 40, 42, 48, 61, 63 and 64 of this patent application.
2. My job responsibilities with respect to Loprox® Shampoo requires me to be familiar with seborrheic dermatitis, available treatments for seborrheic dermatitis, as well as the issues, preferences, and concerns that physicians and patients have concerning seborrheic dermatitis and treatments for it.
3. No other ciclopirox shampoo is currently marketed in the U.S. to date.
4. There are other seborrheic dermatitis treatments on the market in the U.S. They use a variety of active ingredients and delivery vehicles.


5. Seborrheic dermatitis frequently affects highly visible areas of the skin, such as the head (scalp and face) or the hands. Patients regard it as a socially embarrassing, sometimes even a disfiguring disorder. For this reason, physicians and patients place the highest priority on effectiveness, of any treatment for seborrheic dermatitis. Price is often no consideration, or only a distant secondary consideration, in treating seborrheic dermatitis.
6. Loprox® Shampoo is promoted on the basis of its effectiveness, never on the basis of price. In fact, physicians and patients regard Loprox® Shampoo as so effective that Loprox® Shampoo is successfully sold at a premium price. This is further proof that the treatment is effective and only available with Loprox® Shampoo.
7. Loprox® Shampoo is taking market share from its closest competitors as seen in the sales data provided here. Most, if not all of these competitors are less expensive than Loprox® Shampoo. Therefore, it is clear that treatment of seborrheic dermatitis with a 1-hydroxy-2-pyridone (e.g. ciclopirox) composition with no additional actives, a pH between about 4.5 to about 6.5, and a surfactant is really desired by patients and physicians.
8. Loprox® Shampoo is a very successful product. Since January 2005, the market has essentially remained flat (with a 1% decrease in total prescriptions). Loprox® Shampoo's total number of prescriptions grew about 13% from January 2005 to June 2006¹ (when the sales are analyzed at six month intervals).
9. This 13% growth in sales of Loprox® Shampoo occurred at the expense of competitive prescription products. While Loprox® Shampoo sales have grown, the

¹ This is the most current month's data available at this time.

total number of prescriptions in the market has been constant, or slightly declined. (The total number of prescriptions written for products in this market declined 1% from January 2005 to June 2006, when the sales are analyzed at six month intervals). Therefore, the growth in Loprox® Shampoo sales represents a turning away from other treatments and reflects a growing preference for Loprox® Shampoo among physicians and their patients. As I mentioned in Paragraph 5, effectiveness is a paramount concern to physicians and patients. This growth in Loprox® Shampoo sales reflects a judgment by physicians and patients that Loprox® Shampoo is a more effective treatment for seborrheic dermatitis.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application and any registration resulting therefrom.

Date: 9/20/2006


Kevin Kriel